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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,412	01/29/2004	Stephen A. Johnston	UTSD:681USC1	2869

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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,412	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a method of inducing immune response in an animal, classified variously, for example, in class 435, subclass 69.3.

II. Claims 29-30, drawn to a pharmaceutical composition comprising one or more antigen of a pathogen, Mycoplasma pulmonis, classified variously, for example, in class 424, subclass 184.1.

III. Claim 32, drawn to a method of preparing an antigen, classified variously, for example, in class 435, subclass 69.3.

IV. Claim 34, drawn to an antibody, classified variously, for example, in class 530, subclass 387.1.

V. Claim 35, drawn to a kit comprising a cloned genomic expression library, classified variously, for example, in class 536, subclass 23.1.

VI. Claims 36 and 37, drawn to a kit comprising of an antibody, classified in class 435, subclass 130.1.

VII. Claims 38 and 39, drawn to a pharmaceutical composition comprising a cloned expression library, classified variously, for example, in class 435, subclass 320.1.

VIII. Claim 40, drawn to a method of generating an immune response to a tumor cell, classified variously, for example, in class 435, subclass 69.6.

IX. Claim 28, drawn to a method of identifying one of more clones, classified variously, for example, in class 536, subclass 23.1.

X. Claims 29-31, drawn to a pharmaceutical composition comprising one or more antigen of a pathogen, Listeria monocytogenes, classified variously, for example, in class 435, subclass 252.1.

XI. Claim 33, drawn to a method of obtaining an antibody, classified variously, for example, in class 435, subclass 69.6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of (Groups I, III, VIII, IX, and XI) direct to various methods, and (Groups II, IV-VII, and X) direct to various products.

a. Inventions of (Groups VII and V), and (Groups I, VIII, and IX) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product inventions of Groups VII and V direct to cDNA of pathogens and genomic expression library of antigens respectively. Inventions of Group I, VIII, and IX direct to methods of using cDNA or genomic DNA to induce immune response or to identify clones that provide protection against challenge by the pathogen. The products in Groups VII and V can be used in materially different processes such as gene expression,

DNA marker, and hybridization probes. Therefore, the different groups represent patentably distinct subject matter.

b. Inventions of Groups (III & XI) and Groups (II, X, IV & VI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the inventions of Groups III and XI direct to methods of making antigens and antibodies respectively, and inventions of Groups (II & X) and Groups (IV & VI) direct to antigens and antibodies respectively. The antigen products of Groups II & X can be made from solid-phase peptide synthesis, which is a materially different process from the method of Group III. Likewise, the antibodies directed in Groups IV and VI can be generated from a materially different process such as monoclonal antibody techniques.

c. Inventions of (Groups I, VIII, and IX), and (Groups II, X, IV, and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products of Groups (II & X), and (IV & VI) direct to antigens, and antibodies respectively. The invention of Groups I, VIII and IX direct to a method of using cDNA or genomic libraries, which are structurally and functionally different from the products of Groups II, X, IV and VI. In addition, the products of Groups II, X, IV and VI are not required by none of the methods recited in Groups I, VIII and IX.

d. Inventions of Groups (III & XI), and Groups (VII and V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of Groups III and XI methods require materially different products from that of the inventions of Groups V and VII. The "one or more clones of cloned expression library" recited in Group III can be generated from a different expression library (i.e. from a different organism) from that of the one directed in Groups VII and V. Group XI directs to a method of obtaining antibody, which materially different than the products of either Group V or VII.

e. Therefore, the Groups of (I, III, VIII, IX, and XI) and Groups of (II, IV-VII, and X) that describe these methods and products have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different disguising features. Thus, restriction between the groups is proper.

3. Inventions of Groups I, III, VIII, IX, and XI represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group I requires the method step/reagent of "testing the animal for an immune response," which is a step and/or reagent that are not required by none of the Groups III, VIII, IX, and XI. Group III require the step and/or

reagent of "administering to an animal a pharmaceutical composition...", which is a step and/or reagent that are not required by any of the Groups I, VIII, IX and XI. Likewise, Group VIII requires the method step of "preparing a cloned expression library from fragmented cDNA prepared from mammalian tumor mRNA," which is a step and/or reagent that are not required by any of the Groups I, III, IX, and XI. Group IX invention requires "identify one or more clones," which is a step and/or reagent that are not required by any of the Groups I, III, VIII, and XI. Group XI method of obtaining an antibody, which is a step and/or reagent that are not required by any of the Groups I III, VIII, and IX. Therefore, Groups I, III, VIII, and IX represent patentably distinct subject matter and restriction is proper.

4. Inventions of Groups II, IV-VII, and X are unrelated, and represent separate and patentably distinct products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Groups V direct to a composition of a cloned genomic expression library, which could be generated from synthetic nucleic acid fragments, and would be different from the "cloned expression library from cDNA or fragmented genomic DNA" of Group VII. In addition, the nucleic acid sequences of the libraries recited in the libraries of the two Groups could also be different.

Each of the Group V and VII represent materially different products from the antigen (Groups II and X), and antibodies (Group IV and VI) products. Groups II and X antigen products are different functionally and structurally from Groups IV and VI antibodies. The product directed in Group IV is different from the product recited in Group VI, which requires an antibody as well as composition of a pathogen. In addition, the antibodies recited in Groups IV

and VI could be different both functionally and structurally from each other. Group II product directs to antigens derived from Mycoplasma pulmonis. Group X product directs to antigens generated from Listeria moncytogenes, which is materially different from the product drawn in Group II because the antigens from the two groups would be different in terms of their amino acid sequence, functions and structures. Thus, these products represent patentably distinct subject matters, and restriction is proper.

5. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed invention.

If applicants elect any of the invention from Groups I-XI, applicants are requested to further elect a single ultimate species for each of the following:

A.) A single species of animal for generating immune response. (e.g. mouse.)

B.) A single species of either cDNA **OR** fragmented genomic DNA.

C.) A single number of clones introduced into an animal.

D.) A single species of "selected cell" selected from the categories of a pathogen, a tumor cell, **OR** a bacterial cell. Applicants are further requested to select a single ultimate species of a specific species from each of the categories, e.g. adenovirus for virus within the category of pathogen; *Mycoplasma pulmonis* for bacterial cell; breast cancer cell for tumor cell.)

E.) A single species of host cell for preparing cloned expression library selected from the categories of either bacterial **OR** mammalian host cell. Applicants are further requested to select a single ultimate species from each of the categories, e.g. *E. coli.* for bacterial host cell; Hela for mammalian host cell.

F.) A single species of mammalian gene fused to the DNA selected from either ubiquitin **OR** human growth hormone.

G.) A single specie of promoter for expression in a mammalian cell as defined by the said promoter's specific nucleic acid length and sequence.

H.) A single species of signal sequence.

I.) A single species of antigen as defined by its amino acid sequence and length for the pharmaceutical composition.

J.) A single species of antibodies as defined by its specific amino acid sequence and length.

K.) A single range of DNA fragment size selected from the range of 100 to 1000bp. (e.g. about 400bp.)

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they

are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Finally, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sue Liu
Art Unit 1639

PADMASHRI PONNALURI
PRIMARY EXAMINER
7/20/05